IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Simon F. Williams, David P. Martin, and Frank A. Skraly

Serial No.: Divisional of 09/535,146 Art Unit: Not Yet Assigned

#1½

Filed: February 26, 2002 Examiner: Not Yet Assigned

For: *MEDICAL DEVICES AND APPLICATIONS OF POLYHYDROXYALKANOATE POLYMERS*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including eleven (11) pages of Form PTO-1449. The documents cited below were cited by or submitted to the Patent Office in Application Serial No. 09/535,146, filed March 24, 2000, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

Number	Issue Date	Patentee	Class/Subclass
4,792,336	12-20-1988	Hlavacek, et al.	623/13
4,826,493	05-02-1989	Martini, et al.	604/327
4,910,145	03-20-1990	Holmes, et al.	435/259
5,085,629	02-04-1992	Goldberg, et al.	604/8
5,124,371	06-23-1992	Tokiwa et al.	523/124
5,250,430	10-05-1993	Peoples, et al.	435/232
5,271,961	12-21-1993	Mathiowitz, et al.	427/213.31
5,306,286	04-26-1994	Stack, et al.	606/198
5,334,698	08-02-1994	Witholt, et al.	528/354
5,443,458	08-22-1995	Eury	604/891.1
5,480,394	01-02-1996	Ishikawa	604/327
5,480,794	01-02-1996	Peoples, et al.	435/232
5,489,470	02-06-1996	Noda	428/286
5,502,116	03-26-1996	Noda	525/415
5,502,158	03-26-1996	Sinclair et al.	528/354
5,512,669	04-30-1996	Peoples, et al.	536/23.2
5,534,432	07-09-1996	Peoples, et al.	435/240.4
5,536,564	07-16-1996	Noda	428/280
5,551,954	09-03-1996	Buscemi, et al.	623/1
5,563,239	10-08-1996	Hubbs, et al.	528/361
5,625,030	04-29-1997	Williams et al.	528/361
5,629,077	05-13-1997	Turnlund, et al.	442/38
5,646,217	07-08-1997	Hammond	525/450
5,670,161	09-23-1997	Healy, et al.	424/426
5,705,187	01-06-1998	Unger	424/450
5,711,933	01-27-1998	Bichon, et al.	424/9.52
5,814,071	09-29-1998	McDevitt, et al.	606/232
5,824,751	10-20-1998	Hori et al.	525/450
5,834,582	11-10-1998	Sinclair et al.	528/354
5,855,619	01-05-1999	Caplan, et al.	623/11
5,876,452	03-02-1999	Athanasiou, et al.	623/16
5,876,455	03-02-1999	Harwin	623/16
5,935,506	08-10-1999	Schmitz, et al.	264/400
5,994,478	11-30-1999	Asrar, et al.	525/437
6,245,537	06-12-2001	Williams et al.	435/135

Foreign Patent Documents

Number	Publication Date	Patentee	Country
GB 2166354 A	05-08-1986	Imperial Chemical Industries Plc.	UK
0 349 505 A2	03-01-1990	Astra Meditec AB	EP
0 507 554 A1	10-07-1992	Mitsui Toatsu Chemicals, Inc.	EP
0 628 586 A1	06-10-1994	Terumo Kabushiki Kaisha	EP
0 754 467 A1	01-22-1997	Astra Aktiebolag	EP
WO 95/03356 A1	02-02-1995	Massachusetts Institute of Technology	PCT
WO 95/23250 A1	08-31-1995	The Procter & Gamble Co.	PCT
WO 95/33874 A1	12-14-1995	Minnesota Mining & Manufacturing Co.	PCT
WO 96/08535 A1	03-21-1996	The Procter & Gamble Co.	PCT
WO 97/07153 A1	02-27-1997	University of Massachusetts Medical Center	PCT
WO 98/39453 A1	09-11-1998	Monsanto Company	PCT
WO 98/48028 A1	10-29-1998	Monsanto Company	PCT
WO 98/51812 A2	11-19-1998	Metabolix, Inc.	PCT
WO 99/32536 A1	07-01-1999	Metabolix, Inc.	PCT

Publications

AGOSTINI, et al., "Synthesis and Characterization of Poly-ß-Hydroxybutyrate. I. Synthesis of Crystalline DL Poly-ß-Hydroxybutyrate from DL- ß-Butyrolactone," *Polym. Sci., Part A-1* 9:2775-87 (1971).

BAILEY, et al., "Synthesis of Poly- -caprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane," *J. Polym. Sci. Polym. Chem.* 20:3021-30 (1982).

BEHREND, "PHB as a bioresorbable material for intravascular stents," *American J. Cardiol.* p. 45, TCT Abstracts (Oct. 1998).

BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets," *Biotechnology & Bioengineering* 50:562-67 (1996).

BRUHN & MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres," *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.* 18:668-69 (1991).

BYROM, "Miscellaneous Biomaterials," in Biomaterials (D. Byrom, ed.) pp. 333-359 MacMillan Publishers: London, 1991.

CAMPBELL & BAILEY, "Mechanical properties of suture materials *in vitro* and after *in vivo* implantation in horses," *Vet. Surg.* 21(5):355-61 (1992).

CHU, et al., Wound Closure Biomaterials and Devices CRC Press:Boca Raton, 1996.

CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems," *J. Microencapsulation* 9:153-166 (1992).

DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications," *J. Appl. Biomater.* 2(3):187-208 (1991).

DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants," *Biomaterials* 18(8):613-22 (1997).

DOMB, et al., Handbook of Biodegradable Polymers (Harwood Academic Publishers:Amsterdam, The Netherlands, 1997).

DUBOIS, et al., "Macromolecular Engineering of Polylactones and Polylactides. 12. Study of the Depolymerization Reactions of Poly (ε-caprolactone) with Functional Aluminum Alkoxide End Groups," *Macromolecules* 26:4407-12 (1993).

DUVERNOY, et al. "A biodegradable patch used as a pericardial substitute after cardiac surgery: 6- and 24-month evaluation with CT," *Thorac. Cardiovasc. Surg.* 43(5):271-74 (1995).

GABBAY, et al.,"New outlook on pericardial substitution after open heart operations," *Ann. Thorac. Surg.* 48(6):803-12 (1989).

GERNGROSS & MARTIN, "Enzyme-catalyzed synthesis of poly[(R)-(-)-3-hydroxybutyrate]: formation of macroscopic granules *in vitro*," *Proc. Natl. Acad. Sci. USA* 92:6279-83 (1995).

GROSS, et al., "Polymerization of ß-Monosubstituted-ß-propiolactones Using Trialkylaluminum-Water Catalytic Systems and Polymer Characterization," *Macromolecules* 21:2657-68 (1988).

GUGALA, et al., Regeneration of segmental diaphyseal defects in sheep tibiae using resorbable polymeric membranes: a preliminary study," *J. Orthop. Trauma.* 13(3):187-95 (1999).

HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates," *Tissue Eng.* 5(3):187-96 (1999).

HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of *Escherichia coli*," *FEMS Microbiol. Lett.* 153:411-18 (1997).

HEYDORN, et al., "A new look at pericardial substitutes," *J. Thorac. Cardiovasc. Surg.* 94:291-96 (1987).

HOCKING & MARCHESSAULT, "Biopolyesters" in Chemistry and Technology of Biodegradable Polymers, (G.J.L. Griffin, ed.), pp. 48-96, Chapman and Hall: London, 1994.

HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)-ß-hydroxybutyrate] isolated from methyaluminoxane-catalyzed polymerization," *Polym. Bull.* 30:163-70 (1993).

HOLMES, "Biologically Produced (R)-3-hydroxyalkanoate Polymers and Copolymers," in Developments in Crystalline Polymers (Bassett, ed.), pp. 1-65, Elsevier: London, 1988.

HORI, et al., "Ring-Opening Polymerization of Optically Active ß-Butyrolactone Using Distannoxane Catalysts: Synthesis of High Molecular Wright Poly(3-hydroxybutyrate)," *Macromolecules* 26:5533-34 (1993).

HORI, et al., "Ring-Opening Copolymerization of Optically Active ß-Butyrolactone with Several Lactones Catalyzed by Distannoxane Complexes: Synthesis of New Biodegradable Polyesters," *Macromolecules* 26:4388-90 (1993).

HORI, et al., "Chemical synthesis of high molecular weight poly(3-hydroxybutyrate-*co*-4-hydroxybutyrate)," *Polymer* 36:4703-05 (1996).

HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR and GBR applications," *Int. J. Oral Maxillofac. Implants* 11(5):667-78 (1996).

KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly(ß - hydroxybutyrate) by the Tributylin Methoxide Catalyzed Ring-Opening Polymerization of racemic ß-Butyrolactone," *Macromolecules* 26:1221-29 (1993).

KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices," *Chemical and Pharmaceutical Bulletin* 37:1954-56 (1989).

KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier," *Crit. Rev. Ther. Drug Carrier Syst.* 6(2):117-30 (1989).

KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers," Ph.D. Dissertation, 1989, Univ. Nottingham, UK., *Diss. Abstr. Int. B* 51:1206 (1990).

KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]," *Pure Appl. Chem.* A35:319-35 (1998).

LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in Biotechnology (Rehm & Reed, Eds.), pp. 135-76, Verlagsgesellschaft:Weinheim, 1988.

LAMBA, et al., Polyurethanes in Biomedical Applications (CRC Press:Boca Raton, Florida, 1998).

LANZA, et al., Principles of Tissue Engineering (Academic Press:Austin, 1997).

LE BORGNE, et al., "Stereoelective polymerization of ß-butyrolactone," *Polymer* 30:2312-19 (1989).

MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study," *Scand. J. Thorac. Cardiovasc. Surg.* 26(1):9-14 (1992).

MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new biodegradable patch in transannular position," *Eur. Surg. Res.* 26(5):298-308 (1994).

MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study," *J. Thorac. Cardiovasc. Surg.* 104(3):600-07 (1992).

MATHIOWITZ & LANGER, "Polyanhydride microspheres as drug delivery systems" in Microcapsules Nanopart. Med. Pharm. (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).

MAYSINGER, et al., "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS,"*Reviews in the Neurosciences*, 6:15-33 (1995).

MCMILLIN, et al., "Elastomers for Biomedical Applications," *Rubber Chemistry and Technology* 67:417-446 (1994).

MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers," *Angew. Chem. Int. Ed. Engl.* 32:`477-502 (1993).

NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-*co*-4-hydroxybutyrate)," *Macromol.* 25:4237-41 (1992).

NIKLASON, et al., "Functional arteries grown in vitro," *Science* 284(5413):489-93 (1999).

NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems," *Drug Del.* 5:167-77 (1998).

OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid," *Chem. Pharm. Bull.* 36:1095-103 (1988).

OTERA, et al., "Novel template effects of distannoxanne catalysts in highly efficient transesterification and esterification," *J. Org. Chem.* 56:5307-11 (1991).

OTERA, et al., "Distannoxane-catalysed transesterification of 1,*n*-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups," *J. Chem. Soc. Chem. Commun.* 1742-43 (1991).

OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification," *J. Org. Chem.* 54:4013-14 (1989).

OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to , -unsaturated carboxylic acids," *Tetrahedron Lett.*, 27:2383-86 (1986).

POUTON & AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery," *Adv. Drug Delivery Rev.* 18:133-62 (1996).

RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates," *J. Appl. Biomater.* 6(1):65-68 (1995).

SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in *Comamonas acidovorans*," *Int. J. Biol. Macromol.* 16(2):99-104 (1994).

SHINOKA, et al., "Tissue engineering heart valves: valve leaflet replacement study in a lamb model" *Ann. Thorac. Surg.* 60(6 Suppl):S513-16 (1995).

SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering," *J. Thorac. Cardiovasc. Surg.* 115(3):536-46 (1998).

SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in Synthetic Bioabsorbable Polymer Scaffolds (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.

SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate *in vivo*," *Nat. Biotechnol.* 15(1):63-67 (1997).

SPEER & WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials," *Clin. Orthop.* (291):67-74 (1993).

STEINBÜCHEL & VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids," *FEMS Microbiol. Lett.* 128:219-28 (1995).

STEINBÜCHEL & WIESE, "*A Pseudomonas* strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids," *Appl. Microbiol. Biotechnol.* 37:691-97 (1992).

STEINBÜCHEL, "Polyhydroxyalkanoic Acids," in Biomaterials (D. Byrom ed.), pp. 123-213, MacMillan Publishers: London, 1991.

TALJA, et al., "Bioabsorbable and biodegradable stents in urology," *J. Endourol.* 11(6):391-97 (1997).

TANAHASHI, et al., "Thermal Properties and Stereoregularity of Poly(3-hydroxybutyrate) Prepared from optically Active ß-Butyrolactone with a Zinc-Based Catalyst," *Macromolecules* 24:5732-33 (1991).

TANGUAY, et al., "Current status of biodegradable stents," *Cardiol. Clin.* 12(4):699-713 (1994).

TSURUTA, et al., Biomedical Applications of Polymeric Materials (CRC Press, Boca Raton, Florida, 1993).

UNVERDORBEN, et al., "Polyhydroxybutyrate (PHB) Biodegradable Stent-Experience in the Rabbit," *American J. Cardiol.* p. 46, TCT Abstracts (Oct. 1998).

VALENTIN, et al., "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant *Escherichia coli* grown on glucose," *J. Biotechnol.* 58:33-38 (1997).

VON SCHROEDER, et al., "The use of polylactic acid matrix and periosteal grafts for the reconstruction of rabbit knee articular defects," *J. Biomed. Mater. Res.* 25(3):329-39 (1991).

WALLEN & ROHWEDDER, "Poly-ß-hydroxyalakaonate from Activated Sludge," *Environ. Sci. Technol.* 8:576-79 (1974).

WIDMER & MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in Frontiers in Tissue Engineering (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998).

WILLIAMS & PEOPLES, "Making plastics green," *Chem. Br.* 33:29-32 (1997).

WILLIAMS & PEOPLES, "Biodegradable plastics from plants," *CHEMTECH* 26:38-44 (1996).

XIE, et al., "Ring-opening Polymerization of ß-Butyrolactone by Thermophilic Lipases," *Macromolecules* 30:6997-98 (1997).

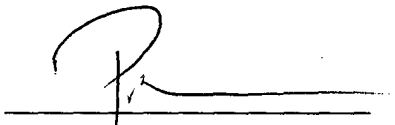
YAMADA, et al., "Development of a dural substitute from synthetic bioabsorbable polymers," *J. Neurosurg.* 86(6):1012-17 (1997).

ZUND, et al., "The in vitro construction of a tissue engineered bioprosthetic heart valve," *Eur. J. Cardiothorac. Surg.* 11(3):493-97 (1997).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: February 26, 2002

HOLLAND & KNIGHT LLP
One Atlantic Center
1201 West Peachtree Street, N.E.
Suite 2000
Atlanta, Georgia 30309-3400
404-817-8500
FAX 404-817-0470
www.hklaw.com

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.10

I hereby certify that this paper and any documents referred to as attached or enclosed are being deposited with the United States Postal Service on this date, February 26, 2002, in an envelope as "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10, Express Mail Label No. EL 639 985 126 US, addressed to Box Patent Application, Commissioner of Patents and Trademarks, Washington, D.C. 20231.

Pam Turnbough

Pam Turnbough

Date: February 26, 2002

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known	
Application Number	Divisional of 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet	1	of	11

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	US Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		4,792,336		Hlavacek, et al.	12-20-1988	
		4,826,493		Martini, et al.	05-02-1989	
		4,910,145		Holmes, et al.	03-20-1990	
		5,085,629		Goldberg, et al.	02-04-1992	
		5,124,371		Tokiwa et al.	06-23-1992	
		5,240,530		Peoples, et al.	10-05-1993	
		5,271,961		Mathiowitz, et al.	12-21-1993	
		5,306,286		Stack, et al.	04-26-1994	
		5,334,698		Witholt, et al.	08-02-1994	
		5,443,458		Eury	08-22-1995	
		5,480,394		Ishikawa	01-02-1996	
		5,480,794		Peoples, et al.	01-02-1996	
		5,489,470		Noda	02-06-1996	
		5,502,116		Noda	03-26-1996	
		5,502,158		Sinclair et al.	03-26-1996	
		5,512,669		Peoples, et al.	04-30-1996	
		5,534,432		Peoples, et al.	07-09-1996	
		5,536,564		Noda	07-16-1996	
		5,551,954		Buscemi, et al.	09-03-1996	
		5,563,239		Hubbs, et al.	10-08-1996	
		5,625,030		Williams et al.	04-29-1997	
		5,629,077		Turnlund, et al.	05-13-1997	
		5,646,217		Hammond	07-08-1997	
		5,670,161		Healy, et al.	09-23-1997	
		5,705,187		Unger	01-06-1998	
		5,711,933		Bichon, et al.	01-27-1998	
		5,814,071		McDevitt, et al.	09-29-1998	
		5,824,751		Hori et al.	10-20-1998	
		5,834,582		Sinclair et al.	11-10-1998	

Examine Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Compl te if Known	
Application Number	Divisional of 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet 2 of 11

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	US Patent Document Number	Kind Code[2] (if known)	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		5,855,619		Caplan, et al.	01-05-1999	
		5,876,452		Athanasiou, et al.	03-02-1999	
		5,876,455		Harwin	03-02-1999	
		5,935,506		Schmitz, et al.	08-10-1999	
		5,994,478		Asrar, et al.	11-30-1999	
		6,245,537		Williams et al.	06-12-2001	

Examine Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known	
Application Number	Divisional f 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet	3	of	11

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		Office.[3]	Number[4]	Kind Code[5] (if known)				
		GB	2166354	A	Imperial Chemical Industries Plc	05-08-1986		
		EP	0 349 505	A2	Astra Meditec AB	03-01-1990		
		EP	0 507 554	A1	Mitsui Toatsu Chemicals, Inc.	10-07-1992		
		EP	0 628 586	A1	Terumo Kabushiki Kaisha	06-10-1994		
		EP	0 754 467	A1	Astra Aktiebolag	01-22-1997		
		WO	95/03356	A1	Massachusetts Institute of Technology	02-02-1995		
		WO	95/23250	A1	The Procter & Gamble Co.	08-31-1995		
		WO	95/33874	A1	Minnesota Mining & Manufacturing Co.	12-14-1995		
		WO	96/08535	A1	The Procter & Gamble Co.	03-21-1996		
		WO	97/07153	A1	University of Massachusetts Medical Center	02-27-1997		
		WO	98/39453	A1	Monsanto Company	09-11-1998		
		WO	98/48028	A1	Monsanto Company	10-29-1998		
		WO	98/51812	A2	Metabolix, Inc.	11-19-1998		
		WO	99/32536	A1	Metabolix, Inc.	07-01-1999		

Examine Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SENT TO: Assistant Commission for Patent, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complet if Known	
Application Number	Divisional of 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet	4	of	11

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		AGOSTINI, et al., "Synthesis and Characterization of Poly-ß-Hydroxybutyrate. I. Synthesis of Crystalline DL Poly-ß-Hydroxybutyrate from DL- ß-Butyrolactone," *Polym. Sci., Part A-1* 9:2775-87 (1971).	
		BAILEY, et al., "Synthesis of Poly- -caprolactone via a free radical mechanism. Free radical ring-opening polymerization of 2-methylene-1,3-dioxepane," *J. Polym. Sci. Polym. Chem.* 20:3021-30 (1982).	
		BEHREND, "PHB as a bioresorbable material for intravascular stents," *American J. Cardiol.* p. 45, TCT Abstracts (Oct. 1998).	
		BREUER, et al., "Tissue Engineering Lamb Heart Valve Leaflets," *Biotechnology & Bioengineering* 50:562-67 (1996).	
		BRUHN & MÜLLER, "Preparation and characterization of spray-dried Poly(DL-Lactide) Micro Spheres," *Proceed. Intern. Symp. Control. Rel. Bioact. Mater.* 18:668-69 (1991).	
		BYROM, "Miscellaneous Biomaterials," in Biomaterials (D. Byrom, ed.) pp. 333-359 MacMillan Publishers: London, 1991.	
		CAMPBELL & BAILEY, "Mechanical properties of suture materials *in vitro* and after *in vivo* implantation in horses," *Vet. Surg.* 21(5):355-61 (1992).	
		CHU, et al., Wound Closure Biomaterials and Devices CRC Press:Boca Raton, 1996.	
		CONTI, et al., "Use of polylactic acid for the preparation of microparticulate drug delivery systems," *J. Microencapsulation* 9:153-166 (1992).	
		DAMIEN & PARSONS, "Bone graft and bone graft substitutes: a review of current technology and applications," *J. Appl. Biomater.* 2(3):187-208 (1991).	
		DE GROOT, "Meniscal tissue regeneration in porous 50/50 copoly(L-lactide/epsilon-caprolactone) implants," *Biomaterials* 18(8):613-22 (1997).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	Divisional of 09/535,146
				Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
				Group Art Unit	
				Examiner Name	
Sheet	5	of	11	Attorney Docket Number	MBX 035 DIV

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		DOMB, et al., Handbook of Biodegradable Polymers (Harwood Academic Publishers:Amsterdam, The Netherlands, 1997).	
		DUBOIS, et al., "Macromolecular Engineering of Polylactones and Polylactides. 12. Study of the Depolymerization Reactions of Poly (ε-caprolactone) with Functional Aluminum Alkoxide End Groups," *Macromolecules* 26:4407-12 (1993).	
		DUVERNOY, et al. "A biodegradable patch used as a pericardial substitute after cardiac surgery: 6- and 24-month evaluation with CT," *Thorac. Cardiovasc. Surg.* 43(5):271-74 (1995).	
		GABBAY, et al., "New outlook on pericardial substitution after open heart operations," *Ann. Thorac. Surg.* 48(6):803-12 (1989).	
		GERNGROSS & MARTIN, "Enzyme-catalyzed synthesis of poly[(R)-(-)-3-hydroxybutyrate]: formation of macroscopic granules *in vitro*," *Proc. Natl. Acad. Sci. USA* 92:6279-83 (1995).	
		GROSS, et al., "Polymerization of ß-Monosubstituted-ß-propiolactones Using Trialkylaluminum-Water Catalytic Systems and Polymer Characterization," *Macromolecules* 21:2657-68 (1988).	
		GUGALA, et al., Regeneration of segmental diaphyseal defects in sheep tibiae using resorbable polymeric membranes: a preliminary study," *J. Orthop. Trauma.* 13(3):187-95 (1999).	
		HADLOCK, et al., "Ocular cell monolayers cultured on biodegradable substrates," *Tissue Eng.* 5(3):187-96 (1999).	
		HEIN, et al., "Biosynthesis of poly(4-hydroxybutyric acid) by recombinant strains of *Escherichia coli*," *FEMS Microbiol. Lett.* 153:411-18 (1997).	
		HEYDORN, et al., "A new look at pericardial substitutes," *J. Thorac. Cardiovasc. Surg.* 94:291-96 (1987).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				**Application Number**	**Divisional of 09/535,146**
				Filing Date	**February 26, 2002**
				First Named Inventor	**Simon F. Williams**
				Group Art Unit	
				Examiner Name	
Sheet	6	of	11	**Attorney Docket Number**	**MBX 035 DIV**

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		HOCKING & MARCHESSAULT, "Syndiotactic poly[(R,S)-ß-hydroxybutyrate] isolated from methyaluminoxane-catalyzed polymerization," *Polym. Bull.* 30:163-70 (1993).	
		HOCKING & MARCHESSAULT, "Biopolyesters" in Chemistry and Technology of Biodegradable Polymers, (G.J.L. Griffin, ed.), pp. 48-96, Chapman and Hall: London, 1994.	
		HOLMES, "Biologically Produced (R)-3-hydroxyalkanoate Polymers and Copolymers," in Developments in Crystalline Polymers (Bassett, ed.), pp. 1-65, Elsevier: London, 1988.	
		HORI, et al., "Chemical synthesis of high molecular weight poly(3-hydroxybutyrate-*co*-4-hydroxybutyrate)," *Polymer* 36:4703-05 (1996).	
		HORI, et al., "Ring-Opening Copolymerization of Optically Active ß-Butyrolactone with Several Lactones Catalyzed by Distannoxane Complexes: Synthesis of New Biodegradable Polyesters," *Macromolecules* 26:4388-90 (1993).	
		HORI, et al., "Ring-Opening Polymerization of Optically Active ß-Butyrolactone Using Distannoxane Catalysts: Synthesis of High Molecular Wright Poly(3-hydroxybutyrate)," *Macromolecules* 26:5533-34 (1993).	
		HUTMACHER, et al., "A review of material properties of biodegradable and bioresorbable polymers and devices for GTR and GBR applications," *Int. J. Oral Maxillofac. Implants* 11(5):667-78 (1996).	
		KEMNITZER, et al., "Preparation of predominantly Syndiotactic Poly(ß -hydroxybutyrate) by the Tributylin Methoxide Catalyzed Ring-Opening Polymerization of racemic ß-Butyrolactone," *Macromolecules* 26:1221-29 (1993).	
		KISHIDA, et al., "Formulation-assisted biodegradable polymer matrices," *Chemical and Pharmaceutical Bulletin* 37:1954-56 (1989).	
		KOOSHA, "Preparation and characterization of biodegradable polymeric drug carriers," Ph.D. Dissertation, 1989, Univ. Nottingham, UK., *Diss. Abstr. Int. B* 51:1206 (1990).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	Divisional of 09/535,146
				Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
				Group Art Unit	
				Examiner Name	
Sheet	7	of	11	Attorney Docket Number	MBX 035 DIV

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		KOOSHA, et al., "Polyhydroxybutyrate as a drug carrier," *Crit. Rev. Ther. Drug Carrier Syst.* 6(2):117-30 (1989).	
		KUSAKA, et al., "Microbial synthesis and Physical Properties of ultra-high-molecular-weight poly[(R)-3-hydroxybutyrate]," *Pure Appl. Chem.* A35:319-35 (1998).	
		LAFFERTY, et al., "Microbial Production of Poly-b-hydroxybutyric acid" in Biotechnology (Rehm & Reed, Eds.), pp. 135-76, Verlagsgesellschaft:Weinheim, 1988.	
		LAMBA, et al., Polyurethanes in Biomedical Applications (CRC Press:Boca Raton, Florida, 1998).	
		LANZA, et al., Principles of Tissue Engineering (Academic Press:Austin, 1997).	
		LE BORGNE, et al., "Stereoelective polymerization of ß-butyrolactone," *Polymer* 30:2312-19 (1989).	
		MALM, et al., "A new biodegradable patch for closure of atrial septal defect. An experimental study," *Scand. J. Thorac. Cardiovasc. Surg.* 26(1):9-14 (1992).	
		MALM, et al., "Enlargement of the right ventricular outflow tract and the pulmonary artery with a new biodegradable patch in transannular position," *Eur. Surg. Res.* 26(5):298-308 (1994).	
		MALM, et al., "Prevention of postoperative pericardial adhesions by closure of the pericardium with absorbable polymer patches. An experimental study," *J. Thorac. Cardiovasc. Surg.* 104(3):600-07 (1992).	
		MATHIOWITZ & LANGER, "Polyanhydride microspheres as drug delivery systems" in Microcapsules Nanopart. Med. Pharm. (Donbrow, ed.), pp. 99-123 (CRC:Boca Raton, Florida, 1992).	
		MAYSINGER, et al., "Microencapsulation and the Grafting of Genetically Transformed Cells as Therapeutic Strategies to rescue Degenerating Neurons of the CNS,"*Reviews in the Neurosciences*, 6:15-33 (1995).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	Divisional of 09/535,146
				Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
				Group Art Unit	
				Examiner Name	
Sheet	8	of	11	Attorney Docket Number	MBX 035 DIV

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		MCMILLIN, et al., "Elastomers for Biomedical Applications," *Rubber Chemistry and Technology* 67:417-46 (1994).	
		MÜLLER, et al., "Poly(hydroxyalkanoates): A Fifth Class of Physiologically Important Organic Biopolymers," *Angew. Chem. Int. Ed. Engl.* 32:477-502 (1993).	
		NAKAMURA, et al., "Microbial synthesis and characterization of poly(3-hydroxybutyrate-*co*-4-hydroxybutyrate)," *Macromol.* 25:4237-41 (1992).	
		NIKLASON, et al., "Functional arteries grown in vitro," *Science* 284(5413):489-93 (1999).	
		NOBES, et al., "Polyhydroxyalkanoates: Materials for delivery systems," *Drug Del.* 5:167-77 (1998).	
		OGAWA, et al., "A New Technique to Efficiently Entrap Leuprolide Acetate into Microcapsules of Poly Lactic Acid or Copoly(Lactic/Glycolic) Acid," *Chem. Pharm. Bull.* 36:1095-103 (1988).	
		OTERA, et al., "Distannoxane as reverse micelle-type catalyst: novel solvent effect on reaction rate of transesterification," *J. Org. Chem.* 54:4013-14 (1989).	
		OTERA, et al., "Distannoxane-catalysed transesterification of 1,*n*-Dioldiacetates. Selective transformation of either of chemically equivalent functional groups," *J. Chem. Soc. Chem. Commun.* 1742-43 (1991).	
		OTERA, et al., "Novel distannoxane-catalyzed transesterification and a new entry to , -unsaturated carboxylic acids," *Tetrahedron Lett.*, 27:2383-86 (1986).	
		OTERA, et al., "Novel template effects of distannoxanne catalysts in highly efficient transesterification and esterification," *J. Org. Chem.* 56:5307-11 (1991).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO				Complet if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Numb r	Divisional f 09/535,146
				Filing Date	February 26, 2002
				First Named Inventor	Simon F. Williams
				Group Art Unit	
				Examiner Name	
Sheet	9	of	11	Attorney Docket Number	MBX 035 DIV

OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		POUTON & AKHTAR, "Biosynthetic polyhydroxyalkanoates and their potential in drug delivery," *Adv. Drug Delivery Rev.* 18:133-62 (1996).	
		RIVARD, et al., "Fibroblast seeding and culture in biodegradable porous substrates," *J. Appl. Biomater.* 6(1):65-68 (1995).	
		SAITO, et al., "Microbial synthesis and properties of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in *Comamonas acidovorans*," *Int. J. Biol. Macromol.* 16(2):99-104 (1994).	
		SHINOKA, et al., "Creation of viable pulmonary artery autografts through tissue engineering," *J. Thorac. Cardiovasc. Surg.* 115(3):536-46 (1998).	
		SHINOKA, et al., "Tissue engineering heart valves: valve leaflet replacement study in a lamb model" *Ann. Thorac. Surg.* 60(6 Suppl):S513-6 (1995).	
		SHINOKA & MAYER, "New frontiers in tissue engineering: tissue engineered heart valves" in Synthetic Bioabsorbable Polymer Scaffolds (Atala & Mooney, eds.) pp. 187-198 Birkhäuser Boston, 1997.	
		SIM, et al., "PHA synthase activity controls the molecular weight and polydispersity of polyhydroxybutyrate *in vivo*," *Nat. Biotechnol.* 15(1):63-67 (1997).	
		SPEER & WARREN, "Arthroscopic shoulder stabilization. A role for biodegradable materials," *Clin. Orthop.* (291):67-74 (1993).	
		STEINBÜCHEL & VALENTIN, "Diversity of bacterial polyhydroxyalkanoic acids," *FEMS Microbiol. Lett.* 128:219-28 (1995).	
		STEINBÜCHEL & WIESE, "*A Pseudomonas* strain accumulating polyesters of 3-hydroxybutyric acid and medium-chain-length 3-hydroxyalkanoic acids," *Appl. Microbiol. Biotechnol.* 37:691-97 (1992).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complet if Kn wn	
Application Number	Divisional of 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet 10 of 11

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		STEINBÜCHEL, "Polyhydroxyalkanoic Acids," in Biomaterials (D. Byrom ed.), pp. 123-213, MacMillan Publishers: London, 1991.	
		TALJA, et al., "Bioabsorbable and biodegradable stents in urology," *J. Endourol.* 11(6):391-97 (1997).	
		TANAHASHI, et al., "Thermal Properties and Stereoregularity of Poly(3-hydroxybutyrate) Prepared from optically Active ß-Butyrolactone with a Zinc-Based Catalyst," *Macromolecules* 24:5732-33 (1991).	
		TANGUAY, et al., "Current status of biodegradable stents," *Cardiol. Clin.* 12(4):699-713 (1994).	
		TSURUTA, et al., Biomedical Applications of Polymeric Materials (CRC Press, Boca Raton, Florida, 1993).	
		UNVERDORBEN, et al., "Polyhydroxybutyrate (PHB) Biodegradable Stent-Experience in the Rabbit," *American J. Cardiol.* p. 46, TCT Abstracts (Oct. 1998).	
		VALENTIN, et al., "Production of poly(3-hydroxybutyrate-co-4-hydroxybutyrate) in recombinant *Escherichia coli* grown on glucose," *J. Biotechnol.* 58:33-38 (1997).	
		VON SCHROEDER, et al., "The use of polylactic acid matrix and periosteal grafts for the reconstruction of rabbit knee articular defects," *J. Biomed. Mater. Res.* 25(3):329-39 (1991).	
		WALLEN & ROHWEDDER, "Poly-ß-hydroxyalakaonate from Activated Sludge," *Environ. Sci. Technol.* 8:576-79 (1974).	
		WIDMER & MIKOS, "Fabrication of biodegradable polymer scaffolds for tissue engineering" in Frontiers in Tissue Engineering (Patrick, et al., Eds.) Ch. II.5, pp.107-20 (Elsevier Science, New York, 1998)	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Please type a plus sign (+) inside this box → [+]

PTO/SB/08A (10-96
Approved for use through 10/31/99. OMB 0651-0031
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Compl te if Known	
Application Number	Divisional of 09/535,146
Filing Date	February 26, 2002
First Named Inventor	Simon F. Williams
Group Art Unit	
Examiner Name	
Attorney Docket Number	MBX 035 DIV

Sheet 11 of 11

OTHER ART – NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T[2]
		WILLIAMS & PEOPLES, "Making plastics green," *Chem. Br.* 33:29-32 (1997).	
		WILLIAMS & PEOPLES, "Biodegradable plastics from plants," *CHEMTECH* 26:38-44 (1996).	
		XIE, et al., "Ring-opening Polymerization of ß-Butyrolactone by Thermophilic Lipases," *Macromolecules* 30:6997-98 (1997).	
		YAMADA, et al., "Development of a dural substitute from synthetic bioabsorbable polymers," *J. Neurosurg.* 86(6):1012-17 (1997).	
		ZUND, et al., "The in vitro construction of a tissue engineered bioprosthetic heart valve," *Eur. J. Cardiothorac. Surg.* 11(3):493-97 (1997).	

Examiner's Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Unique citation designation number [2] See attached Kinds of U.S. Patent Documents. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. [6] Applicant to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you require to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.